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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,176	01/24/2005	Yuuichi Murayama	101551.55779US	7682

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EXAMINER	
JAVANMARD, SAHAR	
ART UNIT	PAPER NUMBER
1627	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,176	MURAYAMA ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6,7,9,13 and 15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 4, 6, 7, 9, 13, and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Office Action is in response to applicant's arguments filed on January 22, 2010. Claim(s) 1, 3, 4, 6, 7, 9, 13, and 15-19 are pending and are examined herein.

Response to Arguments

In view of Applicant's amendments, the 102(b) rejection of claims 7 and 9 as being anticipated by Richardson (WO 96/21437) is moot.

Applicant's arguments with respect to the 103(a) rejection of claims 1, 3, 4, 6, 13, and 15-19 as being unpatentable over Richardson (WO 96/21437) of record as applied to claims 7 and 9 in the 102(b) rejection above in view of Gordon (WO 00/64420) of record has been fully considered but is not persuasive as Applicant is arguing based on amended claims.

Applicant argues that all of Richardson's research is based on subjects not infected with prion proteins and is directed to adjusting the levels of plasma phenylalanine. As previously set forth on record Richardson teaches treating TD by way of example however disorders such as CJD and Hallervorden Spatz disease are a part of the scope of the invention.

Furthermore, although Richardson does not specifically teach "a method of suppressing proliferation of abnormal prion proteins" with essential amino acids, the reference does teach treating abnormal movements in neurological disorders such as Creutzfeld-Jakob

disease (CJD) and Hallervorden Spatz disease, well known in the art to be prion diseases. Therefore, it is Examiner's opinion that although it is not explicitly taught to suppress prion proteins, the same compositions are administered to treat disorders that are of prion origin, thus it will necessarily suppress the proliferation of abnormal prion proteins. Additionally, Applicant argues that Richardson teaches treating subject with TD symptoms (e.g. claim 1) and that CJD is in a laundry list of diseases. This argument is not persuasive. Richardson teaches treating TD by way of example however disorders such as CJD and Hallervorden Spatz disease are a part of the scope of the invention. Applicant refers to the list of diseases as "a laundry list", however, the list is not such that it would pose undue burden to one of ordinary skill in the art to employ the amino acid containing composition to treat disorders such as CJD and Hallervorden Spatz disease. Gordon teaches that neurodegenerative disease Creutzfeldt-Jakob disease is characterized by the appearance and accumulation of a protein-resistant form of a prion protein in the central nervous system in addition to other neurodegenerative diseases including scrapie, bovine spongiform encephalitis, and Gertsmann-Straussler-Scheinker syndrome

The rejection is hereby maintained for reasons of record yet modified in as necessitated by amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 6, 7, 9, 13, and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson (WO 96/21437) of record as applied to claims 7 and 9 in the 102(b) rejection above in view of Gordon (WO 00/64420) of record.

Richardson teaches administration of isoleucine, leucine and/or valine to alleviate abnormal movement disorders (page 10, lines 13-20). Richardson teaches that the total amount of amino acids to be administered of valine, isoleucine and leucine is about 50 to 1500 mg/kg of body weight daily (page 41, lines 6-11). Richardson teaches a method of remitting or attenuating the symptoms of abnormal movement disorders by administering a meal enriched with large neutral amino acids to patients suffering from these disorders (abstract, page 1, lines 1-3).

Richardson teaches a number of neurological disorders that are manifested by abnormal movements, including among many diseases, Creutzfeldt-Jacob disease (page 2, lines 22-33). Richardson further teaches that branched chain amino acids or aromatic acids are administered to alleviate abnormal movement disorders in particular isoleucine, leucine, and valine (page 10, lines 13-21; page 25, example 2; claims).

As discussed above, Richardson teaches that the total amount of amino acids to be administered of valine, isoleucine and leucine is about 50 to 1500 mg/kg of body weight daily (page 41, lines 6-11).

Additionally, Richardson teaches that the branched amino acids can be administered in the form of various pharmaceutical preparations such as tablets, capsules, flavored bars, suspensions, and emulsions (page 41, lines 11-15).

Richardson does not teach neurodegenerative diseases such as scrapie, bovine spongiform encephalitis, and Gertsmann-Straussler-Scheinker syndrome. Furthermore, Richardson is silent on suppressing the proliferation of abnormal prion proteins.

Gordon teaches that neurodegenerative disease Creutzfeldt-Jakob disease is characterized by the appearance and accumulation of a protein-resistant form of a prion protein in the central nervous system (page 1, lines 25-30) in addition to other neurodegenerative diseases including scrapie, bovine spongiform encephalitis, and Gertsmann-Straussler-Scheinker syndrome (page 23, lines 10-12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have administered a meal enriched with large neutral amino acids to patients suffering from disorders such as Creutzfeldt-Jacob disease as taught by Richardson as a method for suppressing the proliferation of abnormal prion proteins. One would be motivated to do so because Richardson teaches treating Creutzfeldt-Jakob disease, a disease that, according to Gordon, is characterized by the appearance and accumulation of a protein-resistant form of a prion protein. Thus it would be obvious that by administering to a patient essential amino acids to treat Creutzfeldt-Jacob disease as taught by Richardson, one would also be suppressing the proliferation of prion proteins. Although Richardson does not explicitly teach the suppression of prion proteins, the same compositions are administered to treat disorders that are of prion

origin, thus it would be obvious to one of ordinary skill in the art to it that it will necessarily suppress the proliferation of abnormal prion proteins. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Furthermore, applying the same rationale, one would expect that diseases such as scrapie, bovine spongiform encephalitis, and Gertsmann-Straussler-Scheinker syndrome as taught by Richardson would also be treated by administering a meal enriched with large neutral amino acids to treat the suppression of abnormal protein prion proliferation because all of these neurodegenerative diseases are characterized by the appearance and accumulation of a protein-resistant form of a prion protein in the central nervous system and it is reasonable to treat diseases that have similar characteristics with similar forms of treatment.

Richardson does not teach wherein the amount of essential amino acid administered is 5-15g/kg.

Richardson teaches doses of 50 to 1500 mg/kg of body weight daily. It would have been obvious to one of ordinary skill in the art at the time of the invention to have

increased the dose. Dosage regimen is a variable that is considered to be well within the purview of the skilled artisan to modify, in the absence of unexpected results.

Conclusion

Claims 1, 3, 4, 6, 7, 9, 13, and 15-19 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627